SENATE BILL NO. 21–COMMITTEE ON HEALTH AND EDUCATION

(ON BEHALF OF THE ATTORNEY GENERAL)

PREFILED DECEMBER 5, 2008

Referred to Committee on Health and Education

SUMMARY—Revises provisions governing the sale or offer for sale of certain food, drugs and other commodities after the date of expiration for those products has passed. (BDR 51-260)

FISCAL NOTE: Effect on Local Government: Increases or Newly Provides for Term of Imprisonment in County or City Jail or Detention Facility.
Effect on the State: Yes.

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EXPLANATION – Matter in ***bolded italics*** is new; matter between brackets [~~omitted material~~] is material to be omitted.

AN ACT relating to commodities; prohibiting the sale or offer for sale of certain drugs, infant formula or baby food if the expiration date for those items has passed; making certain violations deceptive trade practices; providing remedies and penalties; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires the Commissioner of Food and Drugs to inspect and tag food and drugs suspected of being adulterated or misbranded, quarantine the tagged items and destroy them if they are found to be adulterated or misbranded. (NRS 585.250-585.290) This bill requires the Commissioner also to inspect, tag, quarantine and destroy, if necessary, any food or drug which has expired.

Existing law prohibits the sale or offer for sale of any food, drug, device or cosmetic which is adulterated or misbranded. (NRS 585.520) Existing law makes the violation of that prohibition a gross misdemeanor. (NRS 585.550) This bill expands existing law to prohibit the sale or offer for sale of any drug, infant formula or baby food for which the expiration date has passed. This bill also makes any violation of NRS 585.520 a deceptive trade practice and subject to the procedures for administrative enforcement and the remedies and penalties available pursuant to NRS 598.0903 to 598.0999, inclusive, concerning deceptive trade practices. Those remedies and penalties may include the imposition of a temporary or permanent injunction, a civil penalty of up to $10,000 or a criminal penalty up to a category D felony. (NRS 598.0979, 598.0999)

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Chapter 585 of NRS is hereby amended by adding thereto the provisions set forth as sections 2 and 3 of this act.

Sec. 2. ***"Expired" means:***

1. In the case of a drug, that the expiration date required by 21 C.F.R. § 211.137 has passed;

2. In the case of infant formula, that the "use by" date required by 21 C.F.R. § 107.20 has passed; and

3. In the case of baby food, that any expiration date, "use by" date or sale date established by state or federal law or marked on the container by the manufacturer, packer or distributor has passed.

Sec. 3. ***1. Any violation of NRS 585.520 constitutes a deceptive trade practice for the purposes of NRS 598.0903 to 598.0999, inclusive.***

2. The remedies, duties and prohibitions set forth in this chapter for a violation of NRS 585.520 are not exclusive and are in addition to any other remedies, duties and prohibitions provided by law.

Sec. 4. NRS 585.020 is hereby amended to read as follows:

585.020 For the purpose of this chapter, the words and terms defined in NRS 585.030 to 585.150, inclusive, ***and section 2 of this act*** have the meanings ascribed to them in those sections.

Sec. 5. NRS 585.230 is hereby amended to read as follows:

585.230 1. The Commissioner shall keep a record of adulterated, mislabeled ***,*** ~~[or]~~ misbranded ***or expired*** foods, drugs, devices and cosmetics, in which record ~~[shall]~~ ***must*** be included a list of cases examined and violations found and a list of the articles found adulterated, mislabeled ***,*** ~~[or]~~ misbranded ***or expired*** and the names of the manufacturers, producers, jobbers and sellers.

2. The record, or any parts thereof, may, in the discretion of the Commissioner, be included in the biennial report which the Commissioner is authorized to make to the State Board of Health.

3. The Commissioner may also cause to be disseminated such information regarding foods, drugs, devices and cosmetics as he deems necessary in the interest of public health and the protection of the consumer against fraud.

Sec. 6. NRS 585.250 is hereby amended to read as follows:

585.250 1. Whenever the Commissioner, any of his authorized agents, or any member or inspector of the State Board of Pharmacy finds, or has probable cause to believe, that ***, within the***

meaning of this chapter, any food, drug, device or cosmetic is adulterated, or so misbranded as to be dangerous or fraudulent, ~~[within the meaning of this chapter,]~~ ***or that a drug, infant formula or baby food is expired,*** he shall affix to ~~[such]~~ ***the*** article a tag or other appropriate marking, giving notice that ~~[such]~~ ***the*** article is, or is suspected of being, adulterated ***,*** ~~[or]~~ misbranded ***or expired*** and has been quarantined, and warning all persons not to remove or dispose of ~~[such]~~ ***the*** article by sale or otherwise until permission for removal or disposal is given by such agent or the court.

2. It ~~[shall be]~~ ***is*** unlawful for any person to remove or dispose of such ***a*** quarantined article by sale or otherwise without such permission.

Sec. 7. NRS 585.260 is hereby amended to read as follows:

585.260 1. When the Commissioner, his authorized agent, or a member or inspector of the State Board of Pharmacy has found that an article so quarantined is not adulterated ***,*** ~~[or]~~ misbranded ~~[,]~~ ***or expired,*** he shall remove the tag or other marking.

2. In any proceeding against the Commissioner, his authorized agent, or a member or inspector of the State Board of Pharmacy because of such ***a*** quarantine, the Commissioner, his authorized agent, or member or inspector of the State Board of Pharmacy ~~[shall]~~ ***must*** not be held liable if the court ~~[shall find]~~ ***finds*** that there was probable cause for ~~[such]~~ ***the*** quarantine.

Sec. 8. NRS 585.270 is hereby amended to read as follows:

585.270 When an article quarantined under NRS 585.250 has been found by the Commissioner, his authorized agent, or a member or inspector of the State Board of Pharmacy to be adulterated ***,*** ~~[or]~~ misbranded ~~[,]~~ ***or expired,*** the Commissioner, his agent, or such member or inspector shall petition the judge of the district court in whose jurisdiction the article is quarantined for the condemnation and destruction of ~~[such]~~ ***the*** article.

Sec. 9. NRS 585.280 is hereby amended to read as follows:

585.280 If the court finds that a quarantined article is adulterated ***,*** ~~[or]~~ misbranded ~~[, such]~~ ***or expired, the*** article ~~[shall,]~~ ***must,*** after entry of the decree, be destroyed under the supervision of the Commissioner, his authorized agent, or a member or inspector of the State Board of Pharmacy.

Sec. 10. NRS 585.290 is hereby amended to read as follows:

585.290 When the adulteration ***,*** ~~[or]~~ misbranding ***or expiration*** can be corrected by proper labeling or processing of the article to the satisfaction of the Commissioner, his authorized agent, or a member or inspector of the State Board of Pharmacy, the court, after entry of the decree, may by order direct that ~~[such]~~ ***the*** article be delivered to the owner or defender thereof for such labeling or processing under the supervision of the Commissioner, his

authorized agent, or a member or inspector of the State Board of Pharmacy.

Sec. 11. NRS 585.520 is hereby amended to read as follows:

585.520 The following acts and the causing thereof within the State of Nevada are hereby prohibited:

1. The manufacture, sale or delivery, holding or offering for sale of any food, drug, device or cosmetic that is adulterated or misbranded.

2. ***Except as otherwise provided in NRS 597.915 and 639.282, the sale, offering for sale or delivering at retail or to a consumer any drug, infant formula or baby food that is expired.***

3. The adulteration or misbranding of any food, drug, device or cosmetic.

~~[3.]~~ ***4.*** The sale, delivery for sale, holding for sale or offering for sale of any article in violation of NRS 585.490.

~~[4.]~~ ***5.*** The dissemination of any false advertisement.

~~[5.]~~ ***6.*** The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by NRS 585.240 or 585.245.

~~[6.]~~ ***7.*** The giving of a guaranty or undertaking, which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by and containing the name and address of the person residing in the State of Nevada from whom he received in good faith the food, drug, device or cosmetic.

~~[7.]~~ ***8.*** The removal or disposal of a detained or embargoed article in violation of NRS 585.250.

~~[8.]~~ ***9.*** The alteration, mutilation, destruction, obliteration ***, concealment*** or removal ***by any means*** of the whole or any part of the labeling of or the doing of any other act with respect to a food, drug, device or cosmetic, if such act is done while ~~[such]~~ ***the*** article is held for sale and results in ~~[such]~~ ***the*** article being misbranded ~~[.]~~ ***or the passing of the expiration date for the article.***

Sec. 12. NRS 446.920 is hereby amended to read as follows:

446.920 1. Food may be examined or sampled by the health authority as often as may be necessary to determine freedom from adulteration or misbranding. The health authority may, upon written notice to the owner or person in charge, place a hold order on any food which he determines is or has probable cause to believe to be unwholesome or otherwise adulterated ***,*** ~~[or]~~ misbranded ~~[.]~~ ***or expired.***

2. Under a hold order, food ~~[shall]~~ ***must*** be permitted to be suitably stored. It ~~[shall be]~~ ***is*** unlawful for any person to remove or alter a hold order, notice or tag placed on food by the health authority. Neither such food nor the containers thereof ~~[shall]~~ ***may*** be relabeled, repacked, reprocessed, altered, disposed of or

destroyed without permission of the health authority, except by order of a court of competent jurisdiction.

3. After the owner or person in charge has had a hearing as provided for in NRS 446.895, and on the basis of evidence produced at ~~[such]~~ ***the*** hearing, or on the basis of his examination in the event a written request for a hearing is not received within 10 days, the health authority may vacate the hold order, or may by written order direct the owner or person in charge of the food which was placed under the hold order to denature or destroy ~~[such]~~ ***the*** food or to bring it into compliance with the provisions of this chapter. ~~[Such]~~ ***An*** order of the health authority to denature or destroy ~~[such]~~ food or bring it into compliance with the provisions of this chapter ~~[shall]~~ ***must*** be stayed if the order is appealed to a court of competent jurisdiction within 3 days.

Sec. 13. NRS 639.540 is hereby amended to read as follows:

639.540 1. The Board shall ensure the safe and efficient operation of wholesalers and the integrity and propriety of transactions involving the purchase and sale of prescription drugs by wholesalers, including, without limitation, ensuring:

(a) The circumstances and conditions under which a wholesaler must prepare, deliver, acquire and maintain a statement of prior sales regarding a transaction involving the purchase or sale of a prescription drug;

(b) The form and contents of a statement of prior sales; and

(c) The process and procedures for verifying and certifying that the information contained in a statement of prior sales is complete and accurate.

2. In ensuring the circumstances and conditions under which a wholesaler must prepare, deliver, acquire and maintain a statement of prior sales regarding a transaction involving the purchase or sale of a prescription drug, the Board shall consider:

(a) The need for verification to ensure that the transaction is a bona fide transaction pursuant to NRS 639.595; and

(b) The level of risk the transaction poses to public health and safety, including, without limitation, the potential that the transaction may involve the sale or purchase of a prescription drug that is:

(1) Counterfeit;

(2) Deemed to be adulterated ***,*** ~~[or]~~ misbranded ***or expired*** in accordance with the provisions of chapter 585 of NRS;

(3) Mislabeled;

(4) Damaged or compromised by improper handling, storage or temperature control;

(5) From a foreign or unlawful source; or

(6) Manufactured, packaged, labeled or shipped in violation of any state or federal law relating to prescription drugs.

3. If a statement of prior sales is required for a transaction involving the purchase or sale of a prescription drug by a wholesaler, the statement:

(a) Must include the signature of the wholesaler or his designated representative certifying that the information contained in the statement is complete and accurate; and

(b) Except as otherwise provided in subsection 4, must be:

(1) In written or electronic form, if the transaction occurs before January 1, 2007; and

(2) In electronic form, if the transaction occurs on or after January 1, 2007.

4. The Board may extend the date for compliance with the requirement that the statement of prior sales must be in electronic form if the Board determines that the technology to provide such a statement in electronic form is not reasonably available or that the licensed wholesalers in this State otherwise require additional time to carry out the requirements of an electronic form. If the Board extends the deadline pursuant to this subsection, the Board shall ensure that all licensed wholesalers in this State are provided adequate notice of the extension.

Sec. 14. NRS 639.595 is hereby amended to read as follows:

639.595 1. A wholesaler may sell a prescription drug only if the sale is a bona fide transaction.

2. A wholesaler may purchase a prescription drug only from:

(a) A manufacturer;

(b) A pharmacy or practitioner if that pharmacy or practitioner maintains a valid license in the state in which the pharmacy or practitioner is domiciled; or

(c) Another wholesaler if:

(1) The wholesaler who sells the drug is licensed by the Board; and

(2) The sale is a bona fide transaction.

3. A wholesaler may receive a prescription drug from a pharmacy or practitioner only if the wholesaler does not pay the pharmacy or practitioner an amount, either in cash or credit, that is more than the price for which the wholesaler sells such prescription drugs to other pharmacies or practitioners at the time of return and:

(a) The prescription drug was originally shipped to the pharmacy or practitioner by the wholesaler; or

(b) The prescription drug could not be returned by the pharmacy or practitioner to the original wholesaler.

➥ If a wholesaler receives a prescription drug pursuant to this subsection and the wholesaler subsequently sells the prescription

drug to another wholesaler, the prescription drug must be accompanied by a statement of prior sales as defined in NRS 639.535.

4. The Board shall not limit the quantity of prescription drugs a wholesaler may purchase, sell, distribute or otherwise provide to another wholesaler, distributor or manufacturer.

5. For the purposes of this section:

(a) A purchase shall be deemed a bona fide transaction if:

(1) The wholesaler purchased the drug:

(I) Directly from the manufacturer of the drug; or

(II) With a reasonable belief that the drug was originally purchased directly from the manufacturer of the drug;

(2) The circumstances of the purchase reasonably indicate that the drug was not purchased from a source prohibited by law;

(3) Unless the drug is purchased by the wholesaler from the manufacturer, before the wholesaler sells the drug to another wholesaler, the wholesaler who sells the drug conducts a reasonable visual examination of the drug to ensure that the drug is not:

(I) Counterfeit;

(II) Deemed to be adulterated ***,*** ~~[or]~~ misbranded ***or expired*** in accordance with the provisions of chapter 585 of NRS;

(III) Mislabeled;

(IV) Damaged or compromised by improper handling, storage or temperature control;

(V) From a foreign or unlawful source; or

(VI) Manufactured, packaged, labeled or shipped in violation of any state or federal law relating to prescription drugs;

(4) The drug is shipped directly from the wholesaler who sells the drug to the wholesaler who purchases the drug; and

(5) The documents of the shipping company concerning the shipping of the drug are attached to the invoice for the drug and are maintained in the records of the wholesaler.

(b) A sale shall be deemed a bona fide transaction if the wholesaler sells the prescription drug only to:

(1) A pharmacy or practitioner if that pharmacy or practitioner maintains a valid license in the state in which the pharmacy or practitioner is domiciled.

(2) Another wholesaler who maintains a valid license in the state in which he is domiciled if the wholesaler who sells the prescription drug has complied with NRS 639.575, 639.580 and 639.585.

(c) The purchase or sale of a prescription drug includes, without limitation, the distribution, transfer, trading, bartering or any other provision of a prescription drug to another person by a wholesaler. A transfer of a prescription drug from a wholesale facility of a

wholesaler to another wholesale facility of the wholesaler shall not be deemed a purchase or sale of a prescription drug pursuant to this section if the wholesaler is a corporation whose securities are publicly traded and regulated by the Securities Exchange Act of 1934.

Sec. 15. This act becomes effective upon passage and approval.

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